



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV -9 1999

1016 '99 NOV 12 P3:24

The Honorable Richard J. Durbin
United States Senate
Washington, D.C. 20510-1304

Dear Senator Durbin:

Thank you for your letter of October 5, 1999, in which you expressed concern about the lack of a standard of identity for white chocolate. You noted that in March 1997, the Food and Drug Administration (FDA or the Agency) published a proposed rule in the Federal Register to establish a standard of identity for white chocolate but has not taken any subsequent action. You requested that FDA expedite action to establish a standard of identity for white chocolate.

FDA appreciates your concern regarding the establishment of a standard of identity for white chocolate. As you are aware, we tentatively concluded in the proposed rule of March 10, 1997, (62 FR 10781) that creating a standard of identity for white chocolate would promote honesty and fair dealing in the interests of consumers because the standard would eliminate the potential for economic fraud and consumer deception through the substitution of cheaper ingredients for cacao-derived ingredients. Further, we concluded that establishing a standard of identity for white chocolate would alleviate the need for companies to request temporary marketing permits to market white chocolate.

We proposed that a final rule based on this proposed rule would be effective January 1, 1998. While we have reviewed the comments to the white chocolate proposal and have begun drafting a final rule to establish a standard of identity for white chocolate, we have not been able to complete the rulemaking as anticipated due to other work priorities.

As you may know, President Clinton's Food Safety Initiative is the Agency's top priority for FDA's foods program. To accomplish our food safety objectives effectively with our limited resources, we established priorities for FDA's Center for Food Safety and Applied Nutrition (CFSAN). A copy of the "1999 CFSAN Program Priorities" is enclosed.

93P-0091

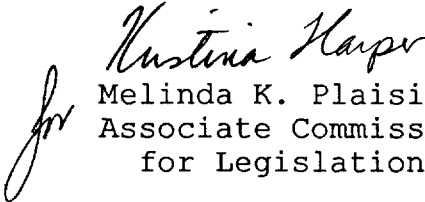
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The rulemaking to establish a standard of identity for white chocolate did not fall within the context of the Food Safety Initiative or other high priorities included in the "1999 CFSAN Program Priorities." We are in the process of identifying CFSAN's priorities for the year 2000. The white chocolate standard is being considered for inclusion in the year 2000 priorities. We are aware of the high interest in this standard and will attempt to complete work on a final rule to establish a standard of identity for white chocolate as our resources permit.

Thank you for your interest in this issue. If we may be of any further assistance, please contact us again.

Sincerely,


Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

cc: Dockets Management Branch
(Dockets Nos. 86P-0297 and 93P-0091)

RICHARD J. DURBIN
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COMMITTEE ON THE JUDICIARY
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October 5, 1999

Jane E. Henney, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
Room 1471 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Henney:

I understand that the Food and Drug Administration (FDA) has taken over six years to act on two petitions requesting that the agency establish a standard of identity for white chocolate. FDA's failure to establish a standard of identity for white chocolate has increased regulatory burdens for white chocolate manufacturers and resulted in higher costs and fewer product choices for consumers.

In March 1997, FDA published in the Federal Register proposed rules to establish a standard of identity for white chocolate. Although your agency announced in its proposed rules that a standard of identity would become effective by January 1, 1998, to date your agency has not acted. Further, in a meeting held with FDA officials in December of 1997, members of the chocolate industry were assured that the white chocolate matter would be resolved by the summer of 1998. Over one year later, FDA has yet to take action.

Because FDA has not developed a standard of identity for white chocolate products, only those companies that apply with the agency to temporarily market those products as "white chocolate" are allowed to use that term in the labeling. In the March 1997 proposed rule, FDA itself acknowledged that the temporary marketing permit (TMP) process has become unnecessarily burdensome, with several companies applying for TMPs in order to market such products. A standard of identity would establish a universal rule for the use of the term "white chocolate" and eliminate the time and expense of obtaining individual TMPs. Consequently, manufacturers would be able to place products on the market faster and at a lower cost to consumers. This standard will also continue to protect against improper use of the value-added term "chocolate."

Lastly, because action by the FDA on this issue would benefit consumers and industry alike, there is no existing opposition to the establishment of a standard of identity for white chocolate. I would therefore appreciate your expedited action on this proposed rule.

Sincerely,



Richard Durbin

No. 99-6467

CROSS FILE SHEET

File Number: 93P-0091/C11

See File Number: 86P-0297/C42